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01/25/02

UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Application of: Ronald M. BURCH, *et al.*
Serial No.: Not yet assigned
Filed: Herewith
For: **ANALGESIC COMBINATION OF OXYCODONE
AND NIMESULIDE**

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents and Trademarks
Washington, D.C. 20231

January 25, 2002

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying PTO-1449 Form for consideration by the Examiner in connection with the examination of the above-noted patent application.

In accordance with 37 C.F.R. § 1.98(d), copies of the listed references are not enclosed as the references cited in the attached Form PTO-1449 have been previously submitted to the PTO or were cited by the Examiner during prosecution of parent application, U.S. Serial No. 09/154,354, entitled, "Analgesic Combination Of Oxycodone And Rofecoxib."

The Examiner's attention is directed to the following copending related applications:

U.S. Serial No. (Not yet known), filed, December 27, 2001, entitled "Analgesic Combination of Oxycodone and Celecoxib",

U.S. Serial No. (Not yet known), filed, January 25, 2002, entitled "Analgesic Combination of Oxycodone and 6-MNA",

U.S. Serial No. (Not yet known), filed, January 25, 2002, entitled "Analgesic Combination of Oxycodone and Nabumetone",

U.S. Serial No. (Not yet known), filed, January 25, 2002, entitled "Analgesic Combination of Oxycodone and Meloxicam",

U.S. Serial No. (Not yet known), filed, January 25, 2002, entitled "Analgesic Combination of Oxycodone and SC-58215" and

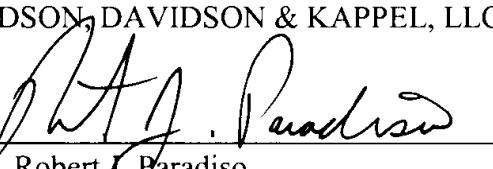
U.S. Serial No. (Not yet known), filed, January 25, 2002, entitled "Analgesic Combination of Oxycodone and T-614".

It is respectfully requested that the references cited in the accompanying PTO-1449 Form be considered and made of record. If any of the publications listed thereon are missing, the Examiner is requested to contact the undersigned so that a copy can be promptly forwarded.

This information disclosure statement is being filed together with the filing of the application and before the mailing date of a first Office Action on the merits. Therefore, under 37 C.F.R. § 1.97 (b), it is believed no fee is required. If it is determined that any fees are due at this time, the Assistant Commissioner is hereby authorized to charge said fees to Deposit Account No. 50-0552.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By _____


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| FORM PTO-1449 (REV. 7-80) | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | | | | | | ATTY. DOCKET NO.: 200.1079CONS | | SERIAL NO.: Not yet known | | | |
|---|----|--|---|---|---|---|---|---|--------------------------------|-----------------|---------------------------------------|----------|----------------------------|----------------------|
| LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary) | | | | | | | | | | | APPLICANT(S): Ronald M. BURCH, et al. | | | |
| | | | | | | | | | | | FILING DATE: Herewith | | | GROUP: Not Yet Known |
| U.S. PATENT DOCUMENTS | | | | | | | | | | | | | | |
| *EXAMINER INITIAL | | DOCUMENT NUMBER | | | | | | | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE | |
| | AA | 5 | 8 | 5 | 9 | 2 | 5 | 7 | 01/12/99 | Talley | 548 | 247 | 08/14/96 | |
| | AB | 5 | 8 | 6 | 3 | 9 | 2 | 2 | 01/26/99 | Mayer, et al. | 514 | 270 | 07/02/99 | |
| | AC | 5 | 8 | 4 | 0 | 7 | 3 | 1 | 11/24/98 | Mayer, et al. | 514 | 289 | 08/02/95 | |
| | AD | 5 | 8 | 6 | 9 | 4 | 9 | 8 | 02/09/99 | Mayer, et al. | 514 | 282 | 07/07/97 | |
| | AE | 5 | 8 | 6 | 1 | 4 | 1 | 9 | 01/19/99 | Dube, et al. | 514 | 334 | 07/11/97 | |
| | AF | 5 | 7 | 8 | 9 | 4 | 1 | 3 | 08/04/98 | Black, et al. | 514 | 255 | 01/21/97 | |
| | AG | 5 | 6 | 0 | 4 | 2 | 6 | 0 | 02/18/97 | Guay, et al. | 514 | 605 | 11/04/93 | |
| | AH | 5 | 4 | 5 | 8 | 8 | 7 | 9 | 10/17/95 | Singh, et al. | 424 | 400 | 09/30/94 | |
| | AI | 5 | 5 | 1 | 6 | 8 | 0 | 3 | 05/14/96 | Raffa | 514 | 570 | 03/01/95 | |
| | AJ | 5 | 8 | 4 | 3 | 4 | 6 | 8 | 12/01/98 | Burkoth, et al. | 424 | 448 | 05/13/96 | |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | | | | | | |
| | AK | <u>Differential Inhibition of Cyclooxygenase-1 (COX-1) and -2 (COX) By NSAIDS: Consequences on Anti-Inflammatory Activity Versus Gastric and Renal Safety.</u> M. Pairet, et al., Inflammopharmacology 4: 61-70, (1996). | | | | | | | | | | | | |
| | AL | <u>Differential effects of inhibitors of cyclooxygenase (cyclooxygenase 1 and cyclooxygenase 2) in acute inflammation,</u> Derek W. Gilroy, et al. European J. Pharm 355 pp 211-217, (1998). | | | | | | | | | | | | |
| | AM | <u>Cyclooxygenases 1 and 2,</u> J.R. Vane, et al. Annu. Rev. Pharmacol. Toxicol. 38: 97-121, (1998). | | | | | | | | | | | | |
| | AN | <u>Analysis of the effects of cyclooxygenase (COX)-1 and COX-2 in spinal nociceptive transmission using indomethacin, a non-selective COX inhibitor, and NS-398, a COX-2 selective inhibitor,</u> Tatsuo Yamamoto, et al. Brain Research 739:104-110, (1996) | | | | | | | | | | | | |
| | AO | <u>Comparative Analgesic Efficacy of Nimesulide and Diclofenac Gels after Topical Application on the Skin,</u> S. Sengupta, et al., Skin Pharmacol. And Applied Skin Phys. 11:273-278, (1998). | | | | | | | | | | | | |
| | AP | <u>Carrageenan-induced hyperalgesia is associated with increased cyclo-oxygenase-2 expression in spinal cord,</u> Cartiona Hay and Jacqueline de Belleroche, Neuro Report 8, 1249-1251, (1997). | | | | | | | | | | | | |
| | AQ | <u>The Mechanisms of Action of NSAIDs in Analgesia,</u> Jeremy N. Cashman, Drugs 52 Supp. 5:13-23, (1996). | | | | | | | | | | | | |
| | AR | <u>Differential effects of inhibition of isoforms of cyclooxygenase (COX-1, COX-2) in chronic inflammation,</u> D.W. Gilroy, et al. Inflamm. Res. 47:79-85, (1998). | | | | | | | | | | | | |
| | AS | <u>Constitutive Cyclooxygenase (COX-1) and Inducible Cyclooxygenase (COX-2): Rationale for Selective Inhibition and Progress to Date,</u> Don E. Griswold and Jerry L. Adams, Medicinal Research Reviews, Vol. 16, No. 2, pp. 181-206, (1996). | | | | | | | | | | | | |
| EXAMINER | | | | | | | | | DATE CONSIDERED | | | | | |
| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | | | | | | | | | | | | | |

| FORM PTO-1449 (REV. 7-80) | | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY. DOCKET NO.: 200.1079CON5 | | SERIAL NO.: Not Yet Known | | |
|---|----|---|--|--|--------------------------------|---------|---------------------------|----------|----------------------------|
| LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary) | | | APPLICANT(S): Ronald M. BURCH, et al. | | | | | | |
| | | | FILING DATE: Not Yet Known | | GROUP: Not Yet Known | | | | |
| U.S. PATENT DOCUMENTS | | | | | | | | | |
| *EXAMINER INITIAL | | DOCUMENT NUMBER | | | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
| BA | | | | | | | | | |
| BB | | | | | | | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | | | | |
| | | DOCUMENT NUMBER | | | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION |
| | | | | | | | | | YES NO |
| BL | | | | | | | | | |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | |
| | BM | Cyclooxygenase in biology and disease, Raymond N. Dubois, et al., FASEB J. Vol. 12 pp. 1063-1073 (1998). | | | | | | | |
| | BN | Pharmacology of Meloxicam, A new Non-Steroidal Anti-Inflammatory Drug With An Improved Safety Profile Through Preferential Inhibition of COX-2, G. Engelhardt, British J. Rheumatology, 35 (supp 1):4-12, (1996) | | | | | | | |
| | BO | Cyclooxygenase 1 Contributes to Inflammatory Responses in Rats and Mice: Implications for Gastrointestinal Toxicity, John L. Wallace, et al. Gastroenterology, 115:101-109 (1998). | | | | | | | |
| | BP | Distinct isoforms (COX-1 and COX-2) of cyclooxygenase: possible physiological and therapeutic implications, M. Pairet and G. Engelhardt, Fundam. Clin. Pharmacol. 10:1-15, (1996). | | | | | | | |
| | BQ | Involvement of Prostaglandins Produced by Cyclooxygenase-1 in Murine Viscernociception Induced by Phenylquinone, Hidenobu Kusuhara, et al. Prostaglandins 55: 43-49, (1998). | | | | | | | |
| | BR | Effect of COX-1 and COX-2 Inhibition on Induction and Maintenance of Carrageenan-Evoked Thermal Hyperalgesia in Rats, D. Dirig, et al. J. Pharmacol. And Experimental Therapeutics Vol. 285, No. 3, pp 1031-1038. | | | | | | | |
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| LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary) | | APPLICANT(S): Ronald M. BURCH, et al. | | | | | | | |
| | | FILING DATE: Not Yet Known | | | GROUP: Not Yet Known | | | | |
| U.S. PATENT DOCUMENTS | | | | | | | | | |
| *EXAMINER INITIAL | | DOCUMENT NUMBER | | | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
| | CA | | | | | | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | | | | |
| | | DOCUMENT NUMBER | | | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION |
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| | CE | 9 | 9 | 0 | 7 | 4 | 1 | 3 | 2/18/99 WO |
| | CF | 9 | 9 | 3 | 2 | 1 | 1 | 9 | 7/1/99 WO |
| | CG | | | | | | | | |
| | CH | | | | | | | | |
| | CI | | | | | | | | |
| | CJ | | | | | | | | |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | |
| | CK | Effect of meloxicam on postoperative pain after abdominal hysterectomy, J.P. Thompson et al. British Journal of Anaesthesia 84 (2) 151-4 (2000). | | | | | | | |
| | CL | Intrathecal cyclooxygenase inhibitor administration attenuates morphine antinociceptive tolerance in rats. C.S. Wong et al., British Journal of Anaesthesia 85 (5) 747-51 (2000). | | | | | | | |
| | CM | Cyclooxygenase inhibitors increase morphine effects on mesolimbic dopamine neurons, M. Melis, et al. Eur. J. Pharmacology 387 (1) R1-R3 (2000). | | | | | | | |
| | CN | Synergistic antialloodynic effects of spinal morphine with ketorolac and selective COX-1 and COX-2 inhibitors in nerve-injured rats, J.M. Lashbrook, et al. Pain 82 (1) 65-72 (1999). | | | | | | | |
| | CO | Enhancement of opioid inhibition of gaba-ergic synaptic transmission by cyclo-oxygenase inhibitors in rat periaqueductal grey neurones, Vaughn et al. British Journal of Pharmacology 123 (8) 1479-81 (1998). | | | | | | | |
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| DA | | 5 | 4 | 7 | 4 | 9 | 9 | 5 | 12/12/95 | Ducharme et al. | 514 | 241 | 01/10/94 | | |
| DB | | 5 | 6 | 9 | 1 | 3 | 7 | 4 | 11/25/97 | Black et al. | 514 | 473 | 05/18/95 | | |
| DC | | | | | | | | | | | | | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | | | | | | | | | | |
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| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | | | | | | | |
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| EA | | 3 | 8 | 0 | 0 | 0 | 4 | 1 | 03/26/74 | Miller, et al. | 424 | 273 | 03/02/71 | |
| EB | | 4 | 3 | 2 | 2 | 4 | 2 | 7 | 03/30/82 | Buyinski, et al. | 424 | 260 | 04/16/81 | |
| EC | | 4 | 3 | 3 | 8 | 3 | 2 | 4 | 06/06/82 | Gardocki | 424 | 266 | 03/17/81 | |
| ED | | 4 | 4 | 0 | 4 | 2 | 1 | 0 | 09/13/83 | Schmidt | 424 | 260 | 06/30/82 | |
| EE | | 4 | 4 | 0 | 7 | 8 | 0 | 4 | 10/04/83 | Schmidt | 424 | 260 | 06/30/82 | |
| EF | | 4 | 4 | 0 | 7 | 8 | 0 | 5 | 10/04/83 | Schmidt | 424 | 260 | 06/30/82 | |
| EG | | 4 | 4 | 6 | 4 | 3 | 7 | 6 | 08/07/84 | Sunshine, et al. | 424 | 253 | 10/11/83 | |
| EH | | 4 | 4 | 8 | 6 | 4 | 3 | 6 | 12/04/84 | Sunshine, et al. | 424 | 253 | 03/11/83 | |
| EI | | 4 | 4 | 8 | 9 | 0 | 8 | 0 | 12/18/84 | Lomen | 424 | 260 | 12/06/82 | |
| FOREIGN PATENT DOCUMENTS | | | | | | | | | | | | | | |
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| | | | | | | | | | | | | | YES | NO |
| EJ | | 2 | 0 | 2 | 3 | 3 | 4 | 9 | 02/18/91 | Canada | A61K | 31/44 | | |
| EK | | 0 | 2 | 7 | 4 | 8 | 4 | 5 | 07/20/88 | EP (A1) | A61K | 31/19 | | |
| EL | | 0 | 3 | 8 | 8 | 1 | 2 | 5 | 09/19/90 | EP (A1) | A61K | 31/485 | | |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | | | | | | |
| EM | | <u>Pharmacokinetics and Drug Input Characteristics for a Diclofenac-Codeine Phosphate Combination Following Oral and Rectal Administration A. Hansen, et al. Arzneim-Forsch./Drug Res. 46 (I) 57-63 (1996).</u> | | | | | | | | | | | | |
| EN | | <u>Comparison of a Standard Ibuprofen Treatment Regimen with a New Ibuprofen/Paracetamol/Codeine Combination in Chronic Osteo-arthritis G.K. Vlok, et al. Univ. Stellenbosch and Tygerberg Hospital, Dept. Orthopaedic Surg. pp 3-6, (1987).</u> | | | | | | | | | | | | |
| EO | | | | | | | | | | | | | | |
| EP | | | | | | | | | | | | | | |
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| FA | | 4 | 5 | 6 | 7 | 1 | 8 | 3 | 01/28/86 | Sunshine, et al. | 514 | 264 | 12/12/83 | | | | | |
| FB | | 4 | 5 | 6 | 9 | 9 | 3 | 7 | 02/11/86 | Baker, et al. | 514 | 282 | 02/11/83 | | | | | |
| FC | | 4 | 5 | 7 | 1 | 4 | 0 | 0 | 02/18/86 | Arnold | 514 | 282 | 12/18/84 | | | | | |
| FD | | 4 | 5 | 8 | 7 | 2 | 5 | 2 | 05/06/86 | Arnold | 514 | 282 | 12/18/84 | | | | | |
| FE | | 4 | 6 | 1 | 9 | 9 | 3 | 4 | 12/28/86 | Sunshine, et al. | 514 | 277 | 07/08/85 | | | | | |
| FF | | 4 | 6 | 9 | 0 | 9 | 2 | 7 | 09/01/87 | Voss, et al. | 514 | 282 | 02/03/86 | | | | | |
| FG | | 4 | 8 | 3 | 9 | 1 | 7 | 6 | 06/13/89 | Pahkhania, et al. | 424 | 465 | 12/08/87 | | | | | |
| FH | | 4 | 8 | 4 | 4 | 9 | 0 | 7 | 07/04/89 | Elger, et al. | 424 | 465 | 08/14/86 | | | | | |
| FI | | 4 | 9 | 2 | 7 | 8 | 5 | 4 | 05/22/90 | Sunshine, et al. | 514 | 570 | 08/21/89 | | | | | |
| FJ | | 5 | 1 | 6 | 4 | 3 | 9 | 8 | 12/17/92 | Sims, et al. | 514 | 282 | 04/01/91 | | | | | |
| FK | | 5 | 1 | 9 | 0 | 9 | 4 | 7 | 03/02/93 | Riess, et al. | 514 | 282 | 08/16/91 | | | | | |
| FL | | 5 | 2 | 4 | 0 | 6 | 9 | 4 | 08/31/93 | Gwaltney, Jr. | 424 | 45 | 12/19/91 | | | | | |
| FOREIGN PATENT DOCUMENTS | | | | | | | | | | | | | | | | | | |
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| FN | | 0 | 0 | 6 | 8 | 8 | 3 | 8 | 06/25/82 | EP (B1) | A61K | 31/485 | | | | | | |
| FO | | 2 | 0 | 8 | 1 | 6 | 0 | 4 | 05/01/95 | Canada | A61K | 031/135 | | | | | | |
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| | GA | 5 | 4 | 0 | 9 | 9 | 4 | 4 | 04/25/95 | Black, et al. | 514 | 359 | 03/12/93 | |
| | GB | 5 | 4 | 3 | 6 | 2 | 6 | 5 | 06/25/95 | Black, et al. | 514 | 420 | 11/12/93 | |
| | GC | 5 | 5 | 1 | 0 | 3 | 6 | 8 | 04/23/96 | Lau, et al. | 514 | 419 | 05/22/95 | |
| | GD | 5 | 5 | 2 | 1 | 2 | 1 | 3 | 05/28/96 | Prasit, et al. | 514 | 443 | 08/29/94 | |
| | GE | 5 | 5 | 5 | 0 | 1 | 4 | 2 | 08/27/96 | Ducharme et al. | 514 | 365 | 05/08/95 | |
| | GF | 5 | 5 | 5 | 2 | 4 | 2 | 2 | 09/03/96 | Gauthier, et al. | 514 | 368 | 01/11/95 | |
| | GG | 5 | 6 | 0 | 4 | 2 | 5 | 3 | 02/18/97 | Lau, et al. | 514 | 415 | 05/22/95 | |
| | GH | 5 | 6 | 3 | 9 | 7 | 8 | 0 | 06/17/97 | Lau, et al. | 514 | 419 | 05/22/95 | |
| FOREIGN PATENT DOCUMENTS | | | | | | | | | | | | | | |
| | | DOCUMENT NUMBER | | | | | | | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | |
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| | GM | | | | | | | | | | | | | |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | | | | | | |
| | GN | Anti-inflammatory Drugs and Their Mechanism of Action J.R. Vane, et al. Inflamm. Res. 47, Supplement 2 (1998). | | | | | | | | | | | | |
| | GO | | | | | | | | | | | | | |
| | GP | | | | | | | | | | | | | |
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| FORM PTO-1449 (REV. 7-80) | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY. DOCKET NO.: 200.1079CONS5 | | SERIAL NO.: Not Yet Known | |
|---|---|--|------|---------------------------------------|-------|---------------------------|----------------------------|
| LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary) | | | | APPLICANT(S): Ronald M. BURCH, et al. | | | |
| | | | | FILING DATE: Not Yet Known | | GROUP: Not Yet Known | |
| U.S. PATENT DOCUMENTS | | | | | | | |
| *EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
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| FOREIGN PATENT DOCUMENTS | | | | | | | |
| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION |
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| | HO | | | | | | |
| | HP | | | | | | |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | |
| HQ | Rorarius et al., "Non-Steroidal Anti-Inflammatory Drugs for PostOperative Pain Relief," Curr. Opin. In Anaesthesiology, 7, 358-362. (1994) | | | | | | |
| HR | Hanses et al. "Pharmacokinetics and Drug input Characteristics for a Diclofenac-Codeine Phosphate Combination Following Oral and Rectal Administration," Arzneim.-Forsch./Drug Res., 46(I), Nr. 1,57-63. (1996) | | | | | | |
| HS | Merck Index, Twelfth Edition, Merck & Co. Publishers, page 1194. (1996) | | | | | | |
| HT | Goodman and Gillman's: Pharmaceutical Basis of Therapeutics, "Chapter 22: Opioid Analgesics and Antagonists", MacMillan Publishing Co., Inc., pp-494-497, esp. Table 22-1, p. 496. (1980) | | | | | | |
| EXAMINER | | | | DATE CONSIDERED | | | |
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